

Remarks/Arguments

In response to the Restriction Requirement, Applicants elect to prosecute the claims of Group I (claims 1-8) in this application. Applicants reserve the right to prosecute cancelled claims 9-15 in further divisional applications. A new claim listing is presented canceling claims 9-15.

Claims 1 and 2 stand rejected under 35 U.S.C. 102(b) as being anticipated by EP 1175915 (hereinafter "the '915 Patent"). Applicants note that Applicants' pending Claim 1 specifically recites "washing" the loaded matrix with a non polar substance. Applicants' specification explains that the claimed composition is produced by first "loading an active compound on a polymeric matrix having ionic functional groups and washing the loaded matrix to remove unbound active... from the matrix." (See page 1, lines 21-25). The process is described in more detail on page 4 of the specification at lines 29-31 where the text specifies that "once the polymer matrix is loaded with an active compound, the loaded matrix is isolated and washed with a solvent..." (emphasis added). From context, one can see that the active is dissolved in a first solution and then exposed to the ion exchange resin. During this process, the active becomes chemically bound to the ion exchange resin. Then the first solution is removed. Next, a second solution without dissolved active can be used to wash unbound active from the surface of the completed active/ion exchange resin. This second step is the "washing" recited in Applicants' claims that is not described in the '915 Patent. Example 3 of Applicants' specification provides a description of a typical "loading and washing" process of this sort.

The term "washed" is thus defined in the specification (and is typically used in this art) to describe a step subsequent to active/ion exchange resin complex formation. In this second step the loaded complex is exposed to a second solvent to remove (i.e., "wash" off) any unbound active. The '915 Patent seems to only describe removing the solvent containing the active to form the complex (see paragraph [0051]). No subsequent washing step is taught or even suggested by the '915 Patent. Whether or not the '915 Patent may describe co-solvents for the first loading solution that are non polar is immaterial because the '915 Patent does not describe "washing [a] loaded matrix" as recited by Claim 1 of Applicants' claims. Therefore, Applicants respectfully request withdrawal of the anticipation rejections of pending claims 1 and 2.

Claims 3-6 stand rejected under 35 U.S.C. §103 as being obvious over the '915 Patent in view of U.S. Patent No. 7,067,116 to BESS et al. (hereinafter BESS). BESS describes forming

complexes of active and ion exchange resin, and then coating such complexes with an outer layer of a water-permeable, diffusion barrier material. (See Col. 10, lines 52-60). Before the complex is coated, it may be "collected and washed with ethanol and/or water to [e]nsure removal of any unabsorbed pharmaceutically active agent." (See Col. 9 at lines 50-53) (Emphasis added). The outer coating is typically a cellulose polymer. (See Col. 11 at lines 10-19). The coating is applied by dissolving it in a solvent before adding it to the active/ion exchange resin complex. (See col. 11, lines 32-41). In her rejection, Applicants believe the Examiner has misconstrued the teachings of the BESS reference. Applicants' claims recite the use of a non polar solvent to wash the loaded matrix. BESS teaches use instead of the polar solvents water and ethanol as "washing" agents. (See BESS at Col. 9, lines 50-54 and compare to Co. 10, lines 52-54 and Col. 11, lines 2-41). BESS only mentions the non polar solvents recited by the Examiner to dissolve outer coating materials that are applied after the optional washing step. BESS does not describe using the mentioned non polar solvents as washing agents. Therefore, the combination of the '915 Patent and the BESS reference suggested by the Examiner would be a process wherein a complex is washed with a polar solvent and subsequently coated by a coating dissolved in a non polar solvent, which would not meet Applicants' claims. In view of the above, Applicants respectfully request the rejection of claims 3-6 be withdrawn.

Claims 7-8 stand rejected as being obvious over '915 in view of BESS. Claims 7-8 depend ultimately from Claim 1 and thus also recite washing with a non polar solvent. This feature is not suggested by either reference and therefore these rejections should also be withdrawn.

Applicants respectfully request reconsideration of the application in view of the above remarks.

Novartis Consumer Health, Inc.
200 Kimball Drive
Parsippany, NJ 07054-0622
(973) 503-7881

Date:

9/18/09

Respectfully submitted,



Frank Smith
Attorney for Applicants
Reg. No. 39,375